REMARKS

The Examiner is requested to consider the accompanying remarks. Reconsideration of the present application is respectfully requested.

Claims 1-39 are in the application for consideration.

Claims 4, 5, 8-10, 13-16, 18-20, and 22-39 are cancelled as belonging to a non-elected invention. The right to pursue these claims in a continuing application is reserved. Applicants request treatment of non-elected process claims as set forth in the *Official Gazette* notice dated March 26, 1996 (1184 O.G. 86). Upon a determination that a product claim is allowable, Applicants request a rejoinder of non-elected process claims and examination of such claims on the merits in the present application.

Claims 1, 2, 6, 11, 17, and 21 have been amended to address objections by the Examiner, correct dependencies, and more distinctly point out that which the applicant regards as the invention. Objection was made to claims 1, 6, 11 and 21 for containing non-elected material. Claims 1, 6, 11, and 21 have been amended to delete the non-elected material. Objection was made to claim 17 for being dependent on a non-elected claim. Claim 17 has been amended to correct dependency. Claims 3, 7 and 12 have been cancelled without prejudice.

New claims 40-43 have been added. Support for the new claims are found in the claims as originally filed.

Three original inventors have been deleted under 37 CFR §1.48(b) who are not inventors of the now claimed subject matter. A petition is attached to this paper identifying each inventor and acknowledging that their invention is no longer being claimed.

The marked-up version of these amendments is found on a separate sheet attached to this amendment and titled **"Version with Markings to Show Changes Made."** It is respectfully requested that the amendments be entered.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1-3, 11-12, 17 and 21 are rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner states: "The applicants do not identify structural features unique to the maize Jip1 promoter that would define or describe DNAs that differ from SEQ ID NO:1, yet retain the maize Jip1 spatial and temporal expression pattern.... Given the lack of description for the maize Jip1 promoter, it remains unclear what features identify a maize Jip1 promoter.... Since a maize Jip1 promoter has not been described by specific structural features or by specific function, the specification fails to provide an adequate written description to support the generic claims.

Claims 3, and 12 have been cancelled without prejudice. Claims 1, 2, 11, 17, and 21 have been amended.

The Federal Register (vol. 66, no. 4, Jan. 5, 2001, page 1106, column 3, third paragraph) recites: "For each claim drawn to a genus: The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice ... reduction to drawings ... *or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristic coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show the applicant was in possession of the claimed genus.*"

The application discloses structure via DNA sequence (SEQ ID NO:1); The application discloses the function correlated with this structure on page 4, lines 28-30: "The Jip1 promoter can address expression problems by providing expression throughout the whole seed over a broad window of development." And again on

page 31, lines 2-3: "Jip1 was predominantly expressed in 15 - 40 DAP embryo with some weaker expression in the endosperm and pericarp."

Physical and chemical properties associated with the claimed sequences are defined by hybridization conditions to the disclosed sequence on page 7, lines 18-20; and by percent identity to the disclosed sequence described on page 8, line 23, through page 9, line 30.

The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "*reasonably* conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." (MPEP 2163.02).

By disclosing the foregoing identifying characteristics, it is believed that one of skill in the art would reasonably conclude that the applicant was in possession of the claimed invention.

The Examiner cites *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), wherein "the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is."

It should be noted that in the above case the claim language focussed on the biological properties of the claimed sequences. In contrast, the limitations of present claim 1 do not focus on biological properties but on structural features such as percent identity and hybridization fidelity. These structural features are readily understood by those practicing the art and are fully supported by the specification as noted above. It is respectfully suggested that: "It may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.'" *In re Grimme*, 274 F2d 949, 952, 124 USPQ 499, 501 (CCPA 1960).

Claims 1-3, 11, 12, 17, and 21 are rejected under 35 USC §112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate scope with these claims.

The Examiner states: "The instant specification ... fails to provide guidance for which base of SEQ ID NO:1 can be altered and still maintain proper spatial and temporal see-preferred expression. The specification also fails to provide guidance for which base can be deleted and which regions of the specification can tolerate additions, base-substitutions or recombinations and still be a functional promoter."

Claims 1, 2, 11, 17, and 21 have been amended. Claim 12 has been cancelled without prejudice.

It is submitted that the specification is fully enabling of present claims 1, 2, 11, 17 and 21 such that one of skill in the art could, without undue experimentation, isolate one or more nucleic acid molecules that: "hybridize to SEQ ID NO: 1, under highly stringent conditions; and ... sequences having at least 65% sequence identity to SEQ ID NO: 1, wherein the % sequence identity is based on the entire sequence and is determined by GAP version 10 analysis using default parameters" that have Jip1 promoter function.

The entire breadth of the claims is supported by the specification as required under 35 USC §112, first paragraph. The specification provides methodology for isolating the promoter from a wide variety of plants and discloses the promoter region of Jip1 in SEQ ID NO:1 (see e.g. page 5, lines 14-26). The specification incorporates by reference commonly available methods for creating variants encompassed by the present claims, such as: progressive deletions (page 10, line 32-page 11, line 9); exonuclease digestion (page 10, lines 20-31). Further provided are reporter genes for assaying promoter function such as GUS (β-glucoronidase) see page 17, lines 3-8. Also provided are methods for determining whether a given

Jip1 promoter variant hybridizes under stringent conditions to a nucleic acid as depicted in SEQ ID NO: 1, (see page 7, lines 18-20).

In total, the specification provides sufficient guidance to one skilled in the art such that they could, through routine protocols, create a panel or library of Jip1 promoter variants and test these promoter variants for Jip1 promoter activity so as to achieve Jip1 promoter variants within the scope of claims 1, 2, 11, 17, and 21.

The Examiner cites Izawa *et al*, Hao *et al*, Busch *et al*, and Lohmann *et al*, to support the position that promoter sequences are intolerant of additions, deletions, and substitutional variations. Applicants respectfully disagree that the references support the Examiner's assertion of non-enablement. Even accepting for the sake of argument that small additions, deletions, and/or substitutions within a Jip1 promoter variant may destroy the promoter variant's activity, it is maintained that it would still be a matter of routine experimentation to create and isolate alternative, functional, Jip1 promoter variants within the scope of the present claims.

It should be noted that the reference of Izawa *et al*, describes the detrimental effects of point mutation on G-box and C-box motifs with regard only to a specific group of proteins: the bZip transcription factors; which are by no means universally necessary for transcription. Indeed, Izawa *et al* state: "Notwithstanding this finding, it is possible that only those proteins that exhibit high affinity for a particular element are physiologically relevant for transcriptional regulation of the cognate element *in vivo*" (page 1132, second column, middle of second paragraph).

The reference by Hao *et al*, relates only to those proteins that contain an ERF domain (see Hao, Abstract). Should the skilled artisan wish to use a Jip1 promoter variant with such a protein, it would not require undue experimentation to conclude whether or not the relevant GCC box had a detrimental point mutation.

The references of Busch *et al* and Lohmann *et al* are found not to be relevant to the issue of base changes within a promoter region as both references describe

base changes within coding regions, not promoter regions. The paragraph in Busch *et al* cited by the Examiner refers to a 2-bp mutation in the *coding* region of the LFY gene.

The Examiner concludes: "Given the unpredictability of determining the function of an isolated nucleic acid other than the 1247 bp's 5' of an isolated maize Jip1 coding region (SEQ ID NO: 1) ... it would require undue experimentation by one skilled in the art to make and/or use the claimed invention."

The Examiner has not presented evidence that would suggest that undue experimentation would be required on the part of the skilled artisan to make and use promoter variants commensurate with the scope of the present claims.

The leading case applying the undue experimentation standard is *In re Wands* where the court held that "[t]he test is not merely quantitative, since *a considerable amount of experimentation is permissible*, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988) [italics added]. The Wands court provided some guidance regarding the amount of experimentation that would be considered "undue" in finding that it is not, for example, undue experimentation for one skilled in the art to isolate a hybridoma cell line, expressing a monoclonal antibody possessing a claimed activity, from a large number of hybridoma cells expressing monoclonal antibodies outside of the recited claim scope. Thus, in rejecting the Patent Office's position that because only 2.8% of the hybridoma cell lines tested fell within the scope of the claim the isolation of inventive hybridoma cell lines was unpredictable, the court emphasized that the skilled artisan, guided by the specification, could nonetheless, reasonably expect to achieve antibodies commensurate with the scope of the claims.

The screening of panels or libraries containing from a few, to many, inoperative species in order to isolate one or more operative species is a common

practice in many aspects of the biotechnological arts. And as the *Wands* court makes clear, this type of experimentation cannot be considered undue, but rather is merely routine experimentation. Thus, it logically follows that the isolation of operative Jip1 promoter variants from a panel or library of candidate promoter variants is not undue experimentation where the Examiner has not put forth any evidence that the number of inoperative species would be significant and where one skilled in the art clearly has a reasonable expectation of success in achieving Jip1 promoter variants that are commensurate in scope with the present claims.

In view of the amendments and remarks, it is submitted that the rejections under 35 USC §112, first paragraph should be withdrawn.

Rejections under 35 USC §112, second paragraph

Claims1-3, and 21 and all subsequent dependent claims are rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner states: "Claim 21 is indefinite as the open language of the claim is confusing and implies that there is another piece of DNA with regulating characteristics that is operably linked to 'a second nucleotide sequence selected from the group consisting of'. Applicants are requested to amend the language of the claim to read on the elected regulatory element operably linked to a specified DNA sequence".

Claim 21 has been amended to read: "wherein the regulatory element comprises a second nucleotide sequence selected from the group consisting of: ....SEQ ID NO:1; ... sequences having at least 65% identity to SEQ ID NO:1 ... sequences that hybridize to SEQ ID NO:1 ... and sequences natively associated with DNA coding for maize Jip1 (jasmonate-induced protein)." It is noted that SEQ ID NO:1 is the elected regulatory element.

The Examiner states: "Claims 1-3 use the abbreviation Jip1 ... this is indefinite as the three letter abbreviation Jip1 is used and refers to JNK-interacting protein.... Using the full name of the gene at least once in the claims would alleviate this problem."

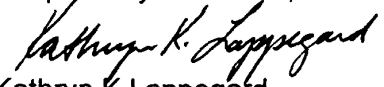
Claim 1 has been amended as suggested by the Examiner to read: "sequences natively associated with DNA coding for maize Jip1 (jasmonate induced protein-1);".

In view of the amendments and remarks, it is submitted that the rejections under 35 USC §112, second paragraph should be withdrawn.

CONCLUSION

In view of the above amendments and remarks, Applicants submit that the rejections of the claims under 35 USC §112, first and second paragraphs, are overcome. Applicants respectfully submit that this application is now in condition for allowance.

Respectfully submitted,



Kathryn K Lappegard
Agent for Applicants
Registration No. 46,857

PIONEER HI-BRED INTERNATIONAL, INC.
Corporate Intellectual Property
7100 N.W. 62nd Avenue
P.O. Box 1000
Johnston, Iowa 50131-1000
Phone: (515) 253-5707
Facsimile: (515) 334-6883

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Claims 3, 4, 5, 7, 8-10, 12, 13-16, 18-20, and 22-39 have been cancelled without prejudice.

Claims 1, 2, 6, 11, 17, and 21 have been amended as follows:

1. (Amended) An isolated regulatory element that is capable of driving transcription in a seed-preferred manner, wherein said regulatory element comprises a nucleotide sequence selected from the group consisting of:
   a) sequences natively associated with DNA coding for maize Jip1 (jasmonate induced protein-1)[, maize mi1ps3, or maize Lec1];
   b) the nucleotide sequence [sequences] set forth in SEQ ID NO: [NOS:] 1[, 4, 7, or 10];
   c) a sequence that hybridizes to [any one of] SEQ ID NO: [NOS:] 1, [4, 7, or 10] under highly stringent conditions; and
   d) a sequence having at least 65% sequence identity to SEQ ID NO: 1, [4, 7, or 10,] wherein the % sequence identity is based on the entire sequence and is determined by GAP version 10 analysis using default parameters.

2. (Amended) An isolated regulatory element that is capable of driving transcription in a seed-preferred manner, wherein said regulatory element comprises a nucleotide sequence natively associated with DNA coding for [any one of] maize Jip1[, maize mi1ps3, or maize Lec1].

6. (Amended) An isolated regulatory element that is capable of driving transcription in a seed-preferred manner, wherein said regulatory element comprises a nucleotide sequence set forth in [any one of] SEQ ID NO: [NOS:] 1[, 4, 7, or 10].

11. (Amended) An isolated regulatory element that is capable of driving transcription in a seed-preferred manner, wherein said regulatory element comprises a sequence that hybridizes to [any one of] SEQ ID NO: [NOS:] 1, [4, 7, or 10] under highly stringent conditions.

17. (Amended) An [The] isolated regulatory element that is capable of driving transcription in a seed-preferred manner, [of claim 16] wherein said regulatory element comprises a sequence having at least 65% sequence identity to SEQ ID NO: 1 wherein the % sequence identity is based on the entire sequence and is determined by GAP version 10 analysis using default parameters.

21. (Amended) An expression cassette comprising a regulatory element and a first nucleotide sequence operably linked to the regulatory element, wherein the regulatory element is capable of initiating seed-preferred transcription of the first nucleotide sequence in a plant cell, wherein the regulatory element comprises a second nucleotide sequence selected from the group consisting of:

a) the nucleotide sequences set forth in [any one of] SEQ ID NO: [NOS:] 1[, 4, 7, or 10];

b) nucleotide sequences having at least 65% sequence identity to SEQ ID NO: [NOS:] 1, [4, 7, or 10,] wherein the % sequence identity is based on the entire sequence and is determined by GAP version 10 analysis using default parameters;

c) a sequence that hybridizes to [any one of] SEQ ID NO: [NOS:] 1, [4, 7, or 10,] under highly stringent conditions[.] ; and

d) a nucleotide sequence natively associated with DNA coding for maize Jip1 (jasmonate-induced protein).

New claims 40-43 have been added as follows:

40. The expression cassette of claim 21, wherein the regulatory element comprises a second nucleotide nativeiy associated with DNA coding for maize Jip1 (jasmonate-induced protein).

41. The expression cassette of claim 21, wherein the regulatory element comprises a second nucleotide sequence comprising a nucleotide sequence set forth in SEQ ID NO: 1.

42. The expression cassette of claim 21, wherein the regulatory element comprises a second nucleotide sequence comprising a nucleotide sequence having at least 65% sequence identity to SEQ ID NO: 1, wherein the % sequence identity is based on the entire sequence and is determined by GAP version 10 analysis using default parameters.

43. The expression cassette of claim 21, wherein the regulatory element is capable of initiating seed-preferred transcription of the first nucleotide sequence in a plant cell, wherein the regulatory element comprises a second nucleotide sequence that hybridizes to SEQ ID NO: 1, under highly stringent conditions.